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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

NGUYEN, DAVE TRONG

ART UNIT PAPER NUMBER

1633

DATE MAILED: 09/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Supplemental
Notice of Allowability**

Application No.

09/677,672

Examiner

Dave T. Nguyen

Applicant(s)

AUDONNET ET AL.

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to _____.
2. ☒ The allowed claim(s) is/are 1,5,6,10,13 and 19.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

Supplemental Examiner' s Amendment

During a review of the as-filed application, the examiner notes that "carbopol", which is a trade name, is used in presently pending claims 1 and 10, which is prohibited under MPEP 2173.05(u). Thus, the following supplemental examiner's amendment is to correct the deficiency. The examiner further notes that in addition to the Declaration of record, which shows the unexpected property as set forth in item (6) of the Declaration, all claims remain allowable because the prior art of record does not teach, suggest or provide a motivation to employ a polymer of acrylic or methacrylic acid as an adjuvant in combination with a naked plasmid DNA, which encodes an antigen of equine rhinopneumonia virus. It is apparent from the art of record that DNA vaccine, which is well-established as being less immunogenic than older style live or killed whole organism vaccines, is highly specialized in their own unique needs in respect of a target species, antigenic component encoded in the DNA vaccine, and a suitable adjuvant employed therein. At the time the invention was made, only strong adjuvants such as alum is employed in exemplifications of DNA vaccines. As such, and let alone the lack of motivation for choosing a specific combination of an antigen of equine rhinopneumonia virus encoded plasmid and a polymeric adjuvant composed of acrylic or methacrylic acid out of many possible choices of adjuvants that have been used in traditional vaccines, one of ordinary skill in the art would not have expected any degree of predictability that such combination would have resulted in an overall increase of neutralizing Ab(s), and a reduction of virus excretion, even though such increase and

Art Unit: 1632

reduction are observed to be a slight improvements over that of DNA vaccines administered alone to equines. Thus, claims 1 (as currently amended below), 5, 6, 10 (as currently amended below), 13 (as currently amended below), and 19 are allowable.

A supplemental examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a personal interview with Attorney Angela M. Collison on July 25, 2005. During the interview, the examiner and applicant agreed that the claims should have been amended to recite the "which is a polymer of acrylic or methacrylic acid" rather than "comprising carbopol" so as to accurately reflect the subject matter of the allowed claim invention. The written support for the newly amended phrase can be found from the originally filed claims.

1. (Currently Amended) A DNA vaccine comprising (i) a naked DNA plasmid containing and expressing *in vivo* a polynucleotide encoding an antigenic polypeptide, wherein the antigenic polypeptide comprises an antigen of equine rhinopneumonia virus; and (ii) at least one adjuvant ~~comprising carbopol~~ which is a polymer of acrylic or methacrylic acid.

10. (Currently Amended) A method of enhancing efficacy of a DNA plasmid vaccine which comprises a naked DNA containing and expressing *in vivo* a heterologous polynucleotide, wherein the heterologous polynucleotide is an immunogen

Art Unit: 1632

of equine rhinopneumonia virus, by adding to the DNA plasmid vaccine Carbopol an
adjuvant which is a polymer of acrylic or methacrylic acid.

13. (Currently Amended) The method of claim 10, wherein the ~~added Carbopol~~
adjuvant has a concentration of 0.06 to 1% w/v.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **571-272-0731**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Central Fax number, which is **571-273-8300**.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Dave Nguyen
Art Unit: 1633



DAVE TRONG NGUYEN
SUPERVISORY PATENT F